UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	)	**MDL No. 16-2740**
	)	**SECTION: "H" (5)**
This document relates to: Barbara Earnest, 16-17144	)	

ORDER AND REASONS

Before the Court is Defendants' Motion for Summary Judgment Based on Preemption (Doc. 6186). The Court heard oral argument on July 25, 2019. For the following reasons, the Motion is **DENIED IN PART** and **DEFERRED IN PART**.

BACKGROUND

Plaintiffs in this multidistrict litigation ("MDL") are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,[1] that Plaintiffs were administered for the treatment of breast cancer and other forms of cancer. Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss. Plaintiffs bring state law claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more.

The first bellwether trial of Plaintiff Barbara Earnest ("Plaintiff") is set to begin September 16, 2019. In the instant Motion, Defendants argue that Plaintiff's claims are preempted. While Defendants raise preemption arguments relating to other Plaintiffs in the MDL, the Court will defer ruling on those arguments until a later date. With regard to Plaintiff Earnest,

[1] Docetaxel is the generic version of Taxotere.

Defendants argue that at the time she was administered Taxotere in 2011, federal law precluded Sanofi from using stronger language in the drug's label.

According to Defendants, the FDA approved the use of Taxotere for advanced or metastatic breast cancer in 1996. The initial labeling identified alopecia as a possible side effect of the drug. Specifically, in an insert for patients, the label listed "Hair Loss" as a side effect and advised that "[l]oss of hair occurs in most patients." The label further told patients that "[o]nce you have completed all your treatments, hair generally grows back." In their briefing, Defendants write that "[t]his FDA-approved language in the patient package insert concerning 'Hair Loss' was the same from the time of initial approval in 1996 until May 2010 when [the] FDA began making class-wide changes to the patient information leaflet for taxanes."

In 2004, Sanofi submitted a supplemental application to the FDA seeking approval to use Taxotere in combination with two other drugs, doxorubicin and cyclophosphamide, for the treatment of patients with operable, "node-positive" breast cancer. With this submission, Sanofi provided the FDA with results from "TAX 316," a clinical study conducted by Sanofi. Notably, the "primary objective" of TAX 316 was to evaluate survival rates, not the occurrence of alopecia.[2] In addition to providing the FDA with the TAX 316 results, Sanofi proposed new label language relating to the new proposed use of the drug. In the "Adverse Reactions" section of the label, Sanofi proposed adding a subsection called "Other persistent reactions." The subsection mentioned alopecia. Defendants aver that after an "extensive series of communications between [the] FDA and Sanofi," the FDA sent Sanofi edits and comments on the proposed revisions to the label. The correspondence shows that an FDA employee named Ann Staten deleted the entire proposed

[2] *See* Doc. 6186-2 at 47.

subsection on "Other persistent reactions." No reason was provided for this deletion. The FDA then approved the supplemental application without the proposed subsection on "Other persistent reactions."

In 2009, Sanofi submitted another supplemental application to the FDA, seeking approval to use Taxotere in combination with doxorubicin and cyclophosphamide for the treatment of patients with operable, "node-negative" breast cancer. This time, Sanofi provided the FDA with the results of another study called the "GEICAM 9805" study. As with the TAX 316 study, the "primary goal" of this study was to evaluate survival rates, not the occurrence of ongoing alopecia. The supplemental application noted that, per the study, 6.1 percent of patients who took a Taxotere-containing regimen had ongoing alopecia compared with 2.9 percent of patients who took another combination. In their briefing, Defendants write that "[t]he supplemental [application] also included proposed changes to the Taxotere label reflecting these findings from the GEICAM 9805 study." Defendants' briefing is unclear on whether these proposed changes were adopted.

Sanofi is vague about whether it submitted the GEICAM 9805 study to the FDA as part of an effort to obtain stronger label language regarding permanent alopecia or whether instead this submission was an "efficacy supplement." In the expert report Sanofi cites on its 2009 dealings with the FDA, the expert writes that "Sanofi withdrew the GEICAM 9805 *efficacy supplement*."[3] (This would explain why Sanofi fails to make clear whether the FDA adopted its "proposed changes" regarding the GEICAM 9805 study.) Notably, Sanofi fails to define for the Court what an "efficacy supplement" is.

[3] Doc. 6186-2 at 54 (emphasis added).

LEGAL STANDARD

Summary judgment is warranted where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."[4] A genuine issue of fact exists only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party."[5] When considering a summary judgment motion, the Court must view the entire record in the light most favorable to the non-moving party and indulge all reasonable inferences in that party's favor.[6]

LAW AND ANALYSIS

"The Supremacy Clause establishes that federal law 'shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.'"[7] Where state and federal law are in direct conflict with each other, "state law must give way."[8] Known as impossibility preemption, this is "a demanding defense," requiring a defendant "to demonstrate that it was impossible to comply with both federal and state requirements."[9]

A preemption analysis must be guided by the two cornerstones of preemption jurisprudence.[10] First, a court should consider "the purpose of Congress."[11] Second, in all preemption cases, a court must assume "that the

[4] FED. R. CIV. P. 56.
[5] Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).
[6] Crawford v. Formosa Plastics Corp., 234 F.3d 899, 902 (5th Cir. 2000).
[7] PLIVA, Inc. v. Mensing, 564 U.S. 604, 617 (2011) (quoting U.S. CONST., Art. VI, cl. 2).
[8] *Id.*
[9] *See* Wyeth v. Levine, 555 U.S. 555, 573 (2009).
[10] *Id.* at 565.
[11] *Id.* (internal citations omitted).

historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress."[12]

In *Wyeth v. Levine*, in considering the "purpose of Congress" behind the FDA, the United States Supreme Court reviewed the history of federal regulation of drugs and drug labeling.[13] In the 1930s, Congress enacted the Federal Food, Drug and Cosmetic Act ("FDCA").[14] The FDCA required every manufacturer to submit a "new drug application" ("NDA") to the FDA for review.[15] In the application, a manufacturer had to include reports of investigations and "specimens of proposed labeling."[16] Until an application became effective, a manufacturer could not distribute a drug.[17] If the FDA determined that a drug was not safe to use as labeled, the FDA could reject an application.[18] If the FDA failed to act on an application, it became effective 60 days after being filed.[19]

In 1962, Congress amended the FDCA and shifted the burden of proof from the FDA to the manufacturer.[20] Under this framework, instead of the FDA proving harm to keep a drug off the market, the manufacturer had to show that its drug was "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling" before distributing the drug.[21] In the 1962 amendments, "Congress took care to preserve state law."[22] The amendments included a clause indicating that "a provision of state law

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[12] *Id.* (internal citations omitted).
[13] *See id.* at 566–68.
[14] *Id.* at 566.
[15] *Id.*
[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Id.* at 567.
[21] *Id.*
[22] *Id.*

would only be invalidated upon a 'direct and positive conflict' with the FDCA."[23]

In 2007, Congress again amended the FDCA, granting the FDA "statutory authority to require a manufacturer to change its drug label based on safety information that becomes available after a drug's initial approval."[24] In doing so, Congress did not require the FDA to preapprove all changes to drug labels.[25] Instead, Congress made clear that manufacturers "remain responsible for updating their labels."[26]

In the instant case, Plaintiff brings a failure to warn claim under the Louisiana Products Liability Act ("LPLA"). "The language of the LPLA provides that a plaintiff may prevail on her failure to warn claim if '[1] the product possessed a characteristic that may cause damage and [2] the manufacturer failed to use reasonable care to provide an adequate warning of such characteristic and its danger to users and handlers of the product.'"[27] Defendants argue that it was impossible to comply with both these state law duties and its federal labeling duties.

Generally, a manufacturer may only change a drug label after the FDA approves a supplemental NDA.[28] However, a manufacturer may make changes to its label prior to receiving FDA approval under the "changes being effected" ("CBE") regulation.[29] Pursuant to the CBE regulation, "if a manufacturer is changing a label to 'add or strengthen a contraindication, warning, precaution, or adverse reaction' or to 'add or strengthen an instruction about dosage and

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[23] *Id.* (quoting the FDCA).
[24] *Id.*
[25] *Id.*
[26] *Id.* at 568.
[27] Grenier v. Med. Eng'g Corp., 243 F. 3d 200, 205 (5th Cir. 2001) (quoting LA. REV. STAT. ANN. § 9:2800.57).
[28] *Levine*, 555 U.S. at 568.
[29] *Id.*

administration that is intended to increase the safe use of the drug product,' it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval."[30]

Like the manufacturer in *Levine*, Sanofi argues that the CBE regulation is not implicated in this case because the regulation provides that a manufacturer may only change its label "to reflect newly acquired information."[31] Sanofi argues that "the plaintiff must show that there existed 'newly acquired information' such that the defendants could unilaterally change the label pursuant to the CBE regulation without prior FDA approval."[32] According to Sanofi, it was impossible to discharge its state law obligation to provide a stronger warning without violating federal law.

Like the manufacturer in *Levine*, "[Sanofi] misapprehends both the federal drug regulatory scheme and its burden in establishing a pre-emption defense." [33] The Supreme Court in *Levine* held that "'newly acquired information' is not limited to new data, but also encompasses 'new analyses of previously submitted data.'"[34] The Court continued:

> The rule accounts for the fact that risk information accumulates over time and that the same data may take on a different meaning in light of subsequent developments: "[I]f the sponsor submits adverse event information to FDA, and then later conducts a new analysis of data showing risks of a different type or of greater severity or frequency than did reports previously submitted to

[30] *Id.* (quoting 21 U.S.C. § 355; 21 CFR §§ 314.70(c)(6)(iii)(A), (C).
[31] *Id.*
[32] Doc. 6186 at 13.
[33] *Levine*, 555 U.S. at 569.
[34] *Id.* (quoting 73 Fed. Reg. 49604).

> FDA, the sponsor meets the requirement for 'newly acquired information.'"[35]

Of course, the FDA retains authority to reject labeling changes made pursuant to the CBE regulation.[36] However, "absent clear evidence that the FDA would not have approved a change to [a manufacturer's] label," a court should not conclude that it was impossible for the manufacturer to comply with both federal and state requirements.[37]

Recently, in *Merck Sharp & Dohme Corp. v. Albrecht*, the Supreme Court considered this "clear evidence" standard. "Clear evidence" is evidence showing that the manufacturer "fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning."[38] Precisely what kind of communications constitute clear evidence of disapproval is a question of law for a judge to decide.[39]

Defendants have failed to demonstrate that the FDA prohibited Sanofi from using stronger language in Taxotere's label. Defendants do not point to any attempted CBE change nor have they presented "clear evidence" that the FDA would not have approved a change to the Taxotere label. They have not shown that Sanofi fully informed the FDA of the justifications for a stronger warning on the risk of permanent alopecia and that the FDA, in turn, decided that it would not approve a change to the label that included the warning. Defendants do not provide the Court with a formal administrative record showing that, as reports of permanent hair loss accumulated, Sanofi alerted the FDA and made a deliberate effort to change the language of the label.

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[35] *Id.* (quoting 73 Fed. Reg. 49607).
[36] *Id.* at 571.
[37] *Id.*
[38] Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1678 (2019).
[39] *See id.* at 1679.

The Court is not persuaded by the evidence that Sanofi has submitted regarding its communications with the FDA in 2004 and 2009. As the Court interprets the evidence, the purpose of these communications was to decide on how to market and label Taxotere for its new uses—the treatment of operable, node-positive breast cancer and operable, node-negative breast cancer. Sanofi was not trying to alert the FDA of an uptick in reports of permanent alopecia but instead trying to expand the distribution of its drug. The references to alopecia appear tangential at best. Indeed, the 2009 submission to the FDA was an "efficacy supplement." Without a better explanation from Sanofi, the Court presumes that the goal of an "efficacy supplement" is to provide evidence of a drug's efficacy, not to alert the FDA of the need for stronger label language.

At oral argument, Defendants' counsel emphasized that the manufacturer provided the FDA with stacks of documents reflecting any information that would have supported stronger label language. Counsel argued that despite having this information the FDA did not request a stronger label. This is a misapplication of the law. As the *Levine* Court wrote, the duty is on the manufacturer, not the FDA, to "craft[] an adequate label and . . . ensur[e] that its warnings remain adequate as long as the drug is on the market."[40] The duty was on Sanofi to alert the FDA about an uptick in reports of permanent alopecia. Accordingly, it is of no moment that Sanofi inundated the FDA with study reports whenever Sanofi was seeking approval to expand the distribution of its drug. This falls short of fully informing the FDA of the justifications for a stronger label.

Defendants have failed to carry their burden of showing that Sanofi was prohibited from adding stronger language to the Taxotere label before

[40] *Levine*, 555 U.S. at 571.

Earnest's treatment in 2011. Accordingly, impossibility preemption does not bar Plaintiff's claims.

CONCLUSION

For the foregoing reasons, **IT IS ORDERED** that Defendants' Motion for Summary Judgment Based on Preemption (Doc. 6186) is **DENIED** insofar as it relates to Plaintiff Barbara Earnest. The Motion is **DEFERRED** insofar as it relates to other Plaintiffs in the MDL.

New Orleans, Louisiana this 14th day of August, 2019.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE